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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,398	06/24/2003	Xiaoyi Min	A03P1046	4855

36802 7590 07/17/2006

PACESETTER, INC.  
15900 VALLEY VIEW COURT  
SYLMAR, CA 91392-9221

EXAMINER
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KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/603,398

Applicant(s)

MIN ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-16,21 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-16, 21, and 23, drawn to a device for detecting ischemia based on T-wave slope and an energy value, classified in class 600, subclass 517.
- II. Claims 17-20 and 22, drawn to a device/method for detecting ischemia based on total T-wave energy, classified in class 600, subclass 516.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a total energy to be determined, but only "an energy value". The subcombination has separate utility such as use in a system that diagnoses ischemia based on T-wave energy alone, not using a maximum slope.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with David Sarisky on 7/5/2006 a provisional election was made without traverse to prosecute the invention of group I, claims 1, 3-16, 21, and 23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-20 and 22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Continued Examination Under 37 CFR 1.114***

6. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/4/2006 has been entered.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "their respective threshold" is lacking antecedent basis.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 3, 5-7, 10-16, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norris et al. (US 6,823,213, hereinafter "Norris") in view of Xue et al. (US 5,792,065, hereinafter "Xue").

12. In regards to claims 1, 3, 5, 7, 15 and 21, Norris discloses the essential features of the claimed invention including: detecting a plurality of T-waves (abstract) and detecting ischemia (col. 1, line 37) based on energy values for the plurality of T-waves (col. 3, line 24) and slopes of the plurality of T-waves (col. 13, line 46), and that these parameters are compared to a threshold (col. 12, line 54) to determine ischemia. Further, Norris discloses that the T-wave detection window is based on a depolarization peak (via US 5,560,370 (col. 14, line 38), incorporated by reference), ectopic beats are discarded (via US 5,560,370 (col. 14, line 36)), and a warning signal is generated by the device (col. 13, line 4). Norris does not expressly disclose that a plurality of slopes for each T-wave are computed and the maximum slope determined, or specifying T-wave windows based on T-wave peaks. Xue teaches of determining a maximum slope of a T-wave (Fig. 7) to provide a means to accurately measure the variability in QT dispersion, and specifying T-wave windows based on T-wave peaks (col. 1, line 26) to accurately determine the T-wave with a variable QT segment. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Norris' invention by determining a maximum slope of a T-wave to provide a means to more accurately measure the T-wave variability to diagnose ischemia, and specifying T-wave windows based on T-wave peaks (col. 1, line 26) to accurately determine the T-wave with a variable QT segment.

13. In regards to claims 6 and 8, the modified invention of Norris discloses the claimed invention, including T-wave peak and depolarization peak-based specification of the T-wave window, but does not disclose expressly the ranges of 150 ms before and

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after the T-wave peak or 80 ms to 480 ms after the depolarization peak. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the T-wave windows as taught by Norris and Xue with the claimed ranges because applicant has not disclosed that the specific range provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the windows as taught by Norris and Xue because both windows contain the T-wave and are used to establish ischemia through T-wave variability. Therefore, it would have been an obvious matter of design choice to modify Norris and Xue's T-wave window to obtain the invention as specified in the claims.

14. In regards to claims 10-14 and 16, Norris' modified invention discloses the essential features of the claimed invention, including ignoring ectopic beats and comparing T-wave energy to a running threshold, but does not explicitly disclose detecting ischemia based on whether the T-waves are paced or sinus beats, normalizing T-wave energy values to depolarization events, ignoring fused beats, or that the warning signal is a different frequency than any other warning signals. It is well known in the art to base therapies and diagnoses on whether a sensed event is paced or intrinsic to account for the different repolarization/response of the heart after paced and intrinsic events; normalizing values to diagnose based on signal morphology without regard to signal amplitude; ignoring fused and other "abnormal" beats to ensure that diagnosis is based on typical beats thus more accurate; and generating warning signal that are different from all other signals to ensure that the intended responder

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recognizes an alarm condition. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Norris' modified invention with a means to base therapies and diagnoses on whether a sensed event is paced or intrinsic to account for the different repolarization/response of the heart after paced and intrinsic events; normalizing values to diagnose based on signal morphology without regard to signal amplitude; ignoring fused and other "abnormal" beats to ensure that diagnosis is based on typical beats thus more accurate; and generating warning signal that are different from all other signals to ensure that the intended responder recognizes an alarm condition.

15. In regards to claim 23, Norris and Xue disclose the claimed invention but does not disclose expressly the product of energy and slope are used for diagnosis. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the energy and slope as taught by Norris and Xue by taking the product because applicant has not disclosed that the product of slope and energy provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the slope-energy variability measure as taught by Norris and Xue because both algorithms consider both the slope and the energy in computing the likelihood of ischemia. Therefore, it would have been an obvious matter of design choice to modify the energy and slope parameters to obtain the invention as specified in the claims.

16. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Norris in view of Xue, as applied to claim 1 above, and further in view of Goldin (US



2002/0151807, hereinafter "Goldin"). Norris' modified invention discloses the essential features of the claimed invention except for sensing bipolar signals in the atrium, sensing unipolar signals elsewhere, and subtracting the bipolar signal from the unipolar signal to sense substantially only ventricular events (par. 0045). Goldin teaches of a method comprising sensing near-field and far-field signals and subtracting the far-field signals to reduce far-field noise. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Norris's invention by sensing bipolar signals in the atrium, sensing unipolar signals elsewhere, and subtracting the bipolar signal from the unipolar signal to signals to reduce far-field noise and sense substantially only ventricular events.

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Norris in view of Xue, as applied to claim 1 above, and further in view of Thiagarajan et al. (US 2003/0060724, hereinafter "Thiagarajan"). The modified invention of Norris discloses the essential features of the claimed invention except for calculating the energy value by calculating the total energy of the T-wave. Thiagarajan teaches of determining the total area of the T-wave to establish a means for comparing T-wave variability (110). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Norris' invention by determining the total area of the T-wave to establish a further means for comparing T-wave variability.

***Response to Arguments***

18. Applicant's arguments with respect to claims 1, 3-16, 21, and 23 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zanetti et al. (US 5,159,932) is one of many teachings of normalizing cardiac signals and Stadler et al. (US 6,381,493) is one of many teachings of diagnosing based on whether beats are paced or sinus and normalizing cardiac signals.

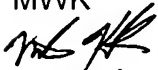
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

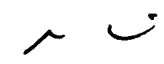
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

  
7/6/06

  
GEORGE R. EVANISKO  
PRIMARY EXAMINER

7/13/06